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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,234	07/28/2003	Don L. Hexamer	118.003	6642

7590 08/11/2005

Irving M. Fishman
89 Headquarters Plaza
Suite 1422, North Tower
Morristown, NJ 07960

EXAMINER	
SINGH, JAI P	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,234	HEXAMER, DON L.	
	Examiner	Art Unit	
	Jai P. Singh	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-37 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20 and 30-32 are drawn to a topical antifungal composition for the treatment of a fungal infection of the skin or nails, or the symptoms associated therewith, in an animal inclusive of human beings in need thereof, classified in class 424, subclasses 404 and 405.

II. Claims 21-29 are drawn to method of making of the topical antifungal composition including a kit containing instructions for reconstitution, classified in class 424, subclasses 51, 52 and 78.08.

III. Claims 30-37 are drawn to method of treating conditions selected from group consisting of bacterial in nature such as Bullous pemphigoid, folliculitis, carbuncles and impetigo, classified in class 424 and subclasses 447, 449, 51 and 52.

IV. Claims 30-37 are drawn to method of treating condition such as psoriasis classified in class 514 and subclass 863.

V. Claims 30 and 33-37 are drawn to method of treating condition such as lyme disease classified in class 514 and subclasses 829 and 830.

VI. Claims 30 and 33-37 are drawn to method of treating condition such as Herpes classified in class 514 and subclass 934.

VII. Claims 30 and 33-37 are drawn to method of treating other conditions such as acne (non-bacterial or fungal) classified in class 514 and subclass 859.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product as evidenced by five methods in groups III-VII (claims 30-37). Claims 30-37 are evidence that the composition of group I can be used in a materially different process of using the composition of group I.

To search and examine more than one invention group would place an undue burden on the examiner. The search for the composition per se is not coextensive with the search for the method inventions. The search for a method of treating antifungal condition is not necessarily related to a search for treating bacterial condition, psoriasis. Similarly the search for treating lyme disease and

herpes are also unrelated with the antifungal, bacterial and other treatment such as acne (not a bacterial or fungal condition) as mentioned in claims 30-37. The search for group I would already be of sufficient burden due to the technology involved and the difficulty involved in searching for the particular features set forth therein. There does not appear to be an effective search method by which to efficiently require hits directed only to such inventive concepts in database searching, and consequently such features must be searched and reviewed line-by-line in the prior art. This time-consuming search burden for group I already places a serious burden on the examiner. Then to place the additional burden of having to search for disparate and divergent therapeutic activities of the composition, each of which require separate searches and separate prior art reviews, rises to the level of burden that would be undue.

Additionally, the anti-fungal composition in claims 1-37 are generic to the plurality of transition metal selected from the group consisting of Ag, Cu, Fe, Ga, Ge, In, Ni, Sn, Ti, Zn, and Zr with halide ions (F, Cl, Br, I) and halophosphates in addition to alcohols such as ethanol, isopropanol, propylene glycol and mixtures thereof. The applicant is required under 35 U.S.C. 121 to elect a single species within a select group (single transition metal associated with single halide and alcohol for the composition), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The search for each individual transition metal and its composition using different halides and alcohol in the composition and its therapeutic value will be extensive because different transition metal compounds are very distinct and have very distinct properties. To search for each transitional metal composition and its therapeutic function will be an undue burden for the examiner.

For these reasons of distinctiveness and undue burden, the restriction requirement as set forth above is deemed proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to Mr. Irving Fishman on July 28, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jai P. Singh whose telephone number is 571-272-8147. The examiner can normally be reached on M-F from 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JPS
8/3/05

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600